UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,746	08/20/2003	Craig C. Mello	UMY-052DV1	9625

959 7590 08/21/2006

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER	
MONSHIPOURI, MARYAM	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,746	MELLO ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,13 and 17-27* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4 and 17-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *filed 6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's response to restriction requirement filed 6/13/2006 is acknowledged. Applicant elected group I, claims 4, 17-27 drawn to RDE-1 polypeptides without traverse. Claims 1-3, 5-12, 14-16 are canceled.

Claim 13 is withdrawn as drawn to non-elected invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4, 17-27 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial or credible asserted utility or a well established utility.

The claimed invention is directed to isolated RDE-1 polypeptides, homologs and fragments thereof, together with fusion products of all said products, for which no substantial and credible utility could be found in the specification. Firsty, In page 2 of the specification applicant refers to RDE-1 polypeptides as RNAi pathway components which provide activities necessary for interference. However the specification does not identify said activities.

Secondly, In page 4 of the specification Figure 4B is describing the predicted amino acid sequence of RDE-1 and is displaying its alignments with F48F7.1 (from C. elegans) and eIF2C (from rabbit) and shows some minor similarities among all said products. However, said similarities are not significant because they are not even 50% and specially they fail to display any shared motifs or regions common to all said products.

Thirdly, in Example 12 applicant teaches identification of potential regions (domains/motifs) involved in creating an RNAi agent utilizing RDE-1 polypeptides but all said methods are hypothetical.

Fourthly a detailed sequence search of said polypeitde failed to display any significant structural similarity to proteins of known function such that at least the examiner could rely on prior art for assigning a utility to the RDE-1 polypeptide of this invention.

Therefore, based on the specification and the state of the prior art at the time of filing, while the examiner fully appreciates that rde-1 gene is positively identified as a constituent of RNAi pathway, she fails to find a credible and substantial utility for the expression product of said gene namely RDE-1 polypeptide (see claim 23-24). The examiner would also like to emphasize that claimed fragments, and homologs of said RED-1 polypeptide (see claims 4, 17-22 and 25) are even more subject to utility rejection because the specification fails to teach which regions of said RDE-1 polypeptide is in charge of assigning function (whatever that may be) to said polypeptide.

Finally since said polypeptide and homologs thereof lack substantial and credible utility their fusion products (claims 26-27) also lack utility.

Claims 4, 17-27 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial or credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In case applicant provides a substantial and credible utility for its RDE-1 polypepitdes the following rejections may apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "high stringency" in claim 4 is indefinite. In page 11 of the specification some examples of "high stringency" conditions are provided but said examples do not specifically define the term used in claim 4.

Claim 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "RDE-1 mutation" in claim 25 (and its dependent claim 26) is confusing. RDE-1 in the spec8fication is referred to expression product of rde-1 gene. It is unclear how a polypeptide can complement a mutated "RDE-1 mutated" polypeptide.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "the polypeitde of claim 4, which hybridizes ...) in claim 17 is unclear. It is indefinite as how polypeitde can hybridize under recited conditions. Usually hybridization is preformed by nucleic acid sequences not by polypeptides.

Claim Rejections - 35 USC § 112

Claims 4, 17-22 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant invention is directed to the following genera of products that have not been adequately defined in the specification:

(1) a **genus** of polypeptides encoded by nucleic acid sequences that hybridize to the complement of SEQ ID NO:2 and their fusion products with no function.

(2) a **genus** of homologs of RDE-1 polypeptides having at least 80% identity to SEQ ID NO:3 and their fusion products with no function.

(3) a **genus** of poplypeptides encoded by a DNA sequences that can complement rde-1 mutations with no function.

(4) a **genus** of polypeptides comprising residues 203-10231 of SEQ ID NO:3 or comprising at least 30 contiguous amino acids of SEQ ID NO:3 with no function.

No functional description has been provided of the homologous sequences shown for parts 1-4 above. No information, beyond the characterization of SEQ ID NO:3 has been provided by applicants which would indicate that they had possession of the claimed genera of modified polypeptides. The specification does not contain any disclosure of the function of all the variant polypeptide sequences derived from SEQ ID NO:3, that are within the scope of the claimed genus. Therefore many functionally

unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a **single species** of the claimed genus (SEQ ID NO:3) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 17-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terms "80%", "95%", "98%", and phrase "at least 30 contiguous amino acids", and "residues 203-1021" in claims 17-22 respectively, were not found to have support in the specification as originally filed. Hence said terms are considered to be **new matter**. Applicant is advised to either direct the examiner to where the support for said terms are provided or possibly delete them from the claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571)

272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Monshy

Maryam Monshipouri Ph.D.

Primary Examiner

***